

Product Name	Company	Application #	Approval Date	Letter Posted	Label Posted	Review Posted
Dacarbazine for Injection USP, 200 mg/vial, Rx	Faulding Pharmaceutical Co.	ANDA 75-940	10/18/01	<u>4/16/03</u>		
Dacarbazine for Injection USP, 500 mg/vial, Rx	Bedford Laboratories	ANDA 75- 812/S3	10/31/02			
Dacarbazine for Injection USP, 200 mg/vial, Rx	Bedford Laboratories	ANDA 75-812	6/15/01	<u>6/26/01</u>		
Dacarbazine for Injection USP, 100 mg/vial & 200 mg/vial	American Pharmaceutical Partners, Inc.	ANDA 75-371	8/27/99	<u>9/2/99</u>		
Dacarbazine for Injection USP, 200 mg/vial, Rx	Gensia Sicor Pharmaceuticals	ANDA 75-259	8/27/98	<u>9/2/98</u>		
Dalmane (flurazepam hydrochloride) Capsules, 15 mg and 30 mg	ICN Pharmaceuticals	NDA 16-721/S- 074	6/14/01	<u>11/22/02</u>		
Daraprim (pyrimethamine) Tablets, 25 mg, Rx	GlaxoSmithKline	NDA 8-578/S- 015	10/10/02	<u>10/21/02</u>	<u>10/10/02</u>	
Darvon Compound 65 (propoxyphene hydrochloride, aspirin and caffeine) Capsule, Darvon (propoxyphene hydrochloride) Capsules, Darvon N (propoxyphene napsylate) Tablets	Lilly Research Laboratories	NDA 10-996/S- 061, 10-997/S- 043 & 16-862/S- 033	8/1/02	<u>8/14/02</u>		
Daunorubicin Hydrochloride for Injection, 5 mg/ml, 4ml vials, Rx	Bedford Laboratories	NDA 50-731	1/30/98			<u>1/7/99</u>
Daunorubicin Hydrochloride for Injection, 20 mg (base)/single dose vial, Rx	Bigmar	ANDA 65-000	5/25/99	<u>5/26/99</u>		
Daunorubicin Hydrochloride for Injection, 20 mg (base)/single dose vial, Rx	Gensia Sicor	ANDA 64-212	6/23/98	<u>6/26/98</u>		
Daunorubicin Hydrochloride Injection, 5 mg (base)/mL, (packaged in 20 mg (base)/4 mL and 50 mg (base)/10 mL single- dose vials), Rx	Gensia Sicor Pharmaceuticals, Inc.	ANDA 65-035	1/24/00	<u>2/4/00</u>		
Daunorubicin Hydrochloride Injection, 5 mg (base)/mL, (packaged in 20 mg (base)/4 mL single-dose vials), Rx	SuperGen, Inc.	ANDA 65-034	11/20/01	<u>10/10/02</u>		

DaunoXome (daunorubicin citrate liposome injection),	Gilead Sciences, Inc.	NDA 50-704/S-008	2/21/02	<u>2/22/02</u>		
Daypro ALTA (oxaprozin potassium) Tablets, 600mg	Pharmacia Corporation	NDA 20-776	10/17/02	<u>10/21/02</u>	<u>11/19/02</u>	
Daypro (Oxaprozin) Caplets, 600 mg	G.D. Searle & Co.	NDA 18-841/S012 & 16	1/25/02	<u>2/4/02</u>	<u>2/4/02</u>	
Daypro (oxyprozin) Caplets, 600 mg	Pharmacia Corporation	NDA 18-841/S-020	4/9/03	<u>4/16/03</u>	<u>4/16/03</u>	
DDAVP (desmopressin acetate) Injection, 4 µg/mL	Aventis Pharmaceutical Products	NDA 18-938/S-017	8/8/02	<u>8/12/02</u>		
Declomycin (demeclocycline hydrochloride) Tablets, Rx	Lederle Laboratories	NDA 50-261/S-095	5/1/03	<u>7/9/03</u>		
DEFINITY Vial for (Perflutren Lipid Microsphere) Injectable Suspension, Rx	Bristol-Myers Squibb Medical Imaging, Inc.	NDA 21-064/SCM-004	1/30/03	<u>2/12/03</u>		
DEFINITY Vial for (Perflutren Lipid Microsphere) Injectable Suspension, Rx	Bristol-Myers Squibb Medical Imaging, Inc.	NDA 21-064/SLR-002	7/8/02	<u>7/9/02</u>		
Definity, Rx	Bristol-Myers Squibb Medical Imaging, Inc.	NDA 21-064/SLR-001	2/21/02	<u>2/21/02</u>		
Definity (perflutren Lipid Microsphere) Injectable Suspension, Rx	DuPont Pharmaceuticals Company	NDA 21-064	7/31/01		<u>05/08/03</u>	<u>11/1/01</u>
Definity Indications: Use of activated Definity (perflutren Lipid Microsphere) Injectable Suspension in patients with suboptimal echocardiograms to opacity the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.						
Delsym (Dextromethorphan Polistirex) Extended-Release Suspension	Celltech Americas, Inc.	NDA 18-658/S015	1/24/02	<u>2/4/02</u>		
Demerol (meperidine HCl) Tablets & Syrup, Rx	Sanofi-Synthelabo	NDA 5-010/S-048	5/15/03	<u>7/9/03</u>		
Demerol (meperidine HCl, USP), Rx	Sanofi-Synthelabo	NDA 5-010/S-047	2/26/03	<u>3/10/03</u>		
Denavir (penciclovir) cream, 1%, Rx	Novartis Consumer Health, Inc.	NDA 20-629/S-009	4/8/03	<u>4/18/03</u>	<u>4/18/03</u>	
Depacon (Valproate Sodium) Injection, Rx	Abbott Laboratories	NDA 20-593/S-006	1/24/02	<u>1/25/02</u>	<u>1/25/02</u>	
Depakene Capsules, Syrup, Tablets, Sprinkle Capsules, and	Abbott Laboratories	NDA 18-081/S-038, 18-082/S-	12/12/02	<u>1/29/03</u>		

Depakote ER Tablets, Rx		024, 18-723/S-029, 19-680/S-015, 20-593/S-009 & 21-168/S-003				
Depakote ER (divalproex) Tablets, Rx	Abbott Laboratories	NDA 21-168/S7	8/14/03	<u>8/15/03</u>		
Depakote ER (divalproex) Extended-Release Tablets, Rx	Abbott Laboratories	NDA 20-782 & 21-168/S4	12/20/02	<u>1/29/03</u>	<u>4/4/03</u>	
Depakote ER (divalproex) Tablets, Rx	Abbott Laboratories	NDA 21-168/S1	5/31/02	<u>6/3/02</u>	<u>5/31/02</u>	
Depakote ER (divalproex sodium extended-release) Tablets, 500mg, Rx	Abbott Laboratories	NDA 21-168	8/4/00	<u>8/17/00</u>	<u>8/17/00</u>	
DepoCyt (Cytarabine Liposomal Injection), 10 mg/mL injection, Rx	DepoTech Corporation	NDA 21-041	4/1/99	<u>4/5/99</u>	<u>4/5/99</u>	<u>7/5/02</u>
Derma-Smoothe/FS (Fluocinolone Acetonide Topical Oil), Rx	Hill Dermaceuticals, Inc.	NDA 19-452/S-018			<u>4/13/03</u>	
Derma-Smoothe/FS (Fluocinolone Acetonide Topical Oil), Rx	Hill Dermaceuticals, Inc.	NDA 19-452/S-17	10/10/01	<u>11/5/01</u>	<u>11/5/01</u>	<u>11/14/01</u>
Derma-Smoothe/FS (Fluocinolone Acetonide Topical Oil), Rx	Hill Dermaceuticals, Inc.	NDA 19-452/S-015	8/19/99	<u>9/24/99</u>	<u>8/24/99</u>	<u>7/3/00</u>
Derma-Smoothe/FS Indication: This supplement approved the treatment of atopic dermatitis in pediatric patients 6 years and older.						
Desferal (deferoxamine mesylate, USP) Injection,	Novartis Pharmaceutical Company	NDA 16-267/S-039	2/14/02	<u>3/8/02</u>		
Desferal (deferoxamine mesylate, USP) Injection,	Novartis Pharmaceutical Company	NDA 16-267/S-034	4/9/01	<u>10/16/02</u>		
Desmopressin Acetate Injection, 4 mcg/mL (packaged in 1 mL ampules), Rx	Abbott Laboratories	ANDA 75-220	8/28/00	<u>10/31/00</u>		
Desmopressin Acetate Injection, 4 mcg/mL (packaged in 10 mL vials), Rx	Bedford Laboratories	ANDA 74-575	2/18/00	<u>2/24/00</u>		
Desmopressin Acetate Injection (Preservative-free), 4 mcg/mL (packaged in 1 mL ampules), Rx	Bedford Laboratories	ANDA 74-574	2/18/00	<u>2/24/00</u>		
Desmopressin Acetate Nasal	Bausch & Lomb	ANDA 74-830	1/25/99	<u>1/25/99</u>		<u>4/22/03</u>

Solution, 0.01%	Pharmaceuticals, Inc.					
Desmopressin Acetate Nasal Spray, Rx	Ferring Pharmaceuticals Inc.	NDA 21-333	9/16/02	<u>9/20/02</u>	<u>9/17/02</u>	
Desogestrel & Ethinyl Estradiol Tablets, 0.15 mg & 0.03, respectively, Rx <i>Tentatively Approved</i>	Duramed Pharmaceuticals	ANDA 75-863	11/29/01	<u>4/15/03</u>		
Desogestrel & Ethinyl Estradiol Tablets, 0.15 mg & 0.03, respectively	Duramed Pharmaceuticals	ANDA 75-256/S7	06/19/02	<u>8/24/99</u>		<u>8/6/03</u>
Desogestrel & Ethinyl Estradiol Tablets, 0.15 mg & 0.03, respectively	Duramed Pharmaceuticals	ANDA 75-256/S6	07/27/01	<u>8/24/99</u>		<u>8/6/03</u>
Desogestrel & Ethinyl Estradiol Tablets, 0.15 mg & 0.03, respectively	Duramed Pharmaceuticals	ANDA 75-256/S5	07/27/01	<u>8/24/99</u>		<u>8/6/03</u>
Desogestrel & Ethinyl Estradiol Tablets, 0.15 mg & 0.03, respectively	Duramed Pharmaceuticals	ANDA 75-256/S4	07/11/01	<u>8/24/99</u>		<u>8/6/03</u>
Desogestrel & Ethinyl Estradiol Tablets, 0.15 mg & 0.03, respectively	Duramed Pharmaceuticals	ANDA 75-256/S3	11/14/01	<u>8/24/99</u>		<u>8/6/03</u>
Desogestrel & Ethinyl Estradiol Tablets, 0.15 mg & 0.03, respectively	Duramed Pharmaceuticals	ANDA 75-256/S2	06/28/01	<u>8/24/99</u>		<u>8/6/03</u>
Desogestrel & Ethinyl Estradiol Tablets, 0.15 mg & 0.03, respectively	Duramed Pharmaceuticals	ANDA 75-256/S1	10/28/99	<u>8/24/99</u>		<u>8/6/03</u>
Desogestrel & Ethinyl Estradiol Tablets, 0.15 mg & 0.03, respectively	Duramed Pharmaceuticals	ANDA 75-256	8/12/99	<u>8/24/99</u>		<u>8/6/03</u>
Desonide Lotion, 0.05%, Rx	Altana Inc.	ANDA 75-860	3/19/02	<u>4/10/03</u>		
Desonide Ointment, 0.05%, Rx	Altana Inc.	ANDA 75-751	3/12/01	<u>3/30/01</u>		<u>1/17/02</u>
Desoximetasone Cream USP, 0.25%	Clay Park Labs, Inc.	ANDA 76-510	6/1/03			
Desoximetasone Ointment USP, 0.25%	Altana Inc.	ANDA 73-440	4/1/98			<u>2/22/99</u>
Desoximetasone Gel+- USP, 0.5%	Taro Pharmaceuticals USA, Inc.	ANDA 74-904	7/14/98	<u>7/14/98</u>		<u>3/16/99</u>
Desoxyn (methamphetamine HCl) Tablets and Desoxyn (methamphetamine HCl)	Abbott Laboratories	NDA 5-378/S-020	12/6/01		<u>4/3/03</u>	

Gradumet Tablets, 5 mg & 5 mg, 10 mg, and 15 mg, Rx						
Detrol LA Extended Release Capsules, Rx	Pharmacia and Upjohn	NDA 21-228/S4	7/21/03	<u>7/28/03</u>		
Detrol LA Capsules, 2 and 4 mg extended release, Rx	Pharmacia and Upjohn	NDA 21-228/S1	4/27/01		<u>5/1/03</u>	
Detrol LA Capsules, 2 and 4 mg extended release, Rx	Pharmacia and Upjohn	NDA 21-228	12/22/00	<u>1/9/01</u>	<u>1/9/01</u>	
	Detrol Indications: overactive bladder with symptoms of urge urinary incontinence, urgency and frequency					
Detrol (Tolterodine Tartrate) Tablets, Rx	Pharmacia and Upjohn	NDA 20-771/S-010	7/21/03	<u>7/28/03</u>		
Detrol (Tolterodine Tartrate) Tablets, 1 and 2 mg, Rx	Pharmacia and Upjohn	NDA 20-771/S-004	4/6/01	<u>4/9/01</u>	<u>4/9/01</u>	
Detrol (Tolterodine Tartrate), 1 and 2 mg	Pharmacia and Upjohn	NDA 20-771	3/25/98	<u>9/24/98</u>	<u>6/25/98</u>	<u>7/3/00</u>
Dexamethasone Sodium Phosphate Injection, 10 mg, Rx	American Pharmaceutical	ANDA 40-491	4/11/03	<u>1/14/02</u>		
Dexmethylphenidate HCl Tablets	Celgene	NDA 21-278	11/13/01			
Dextroamphetamine Sulfate Extended Release Capsules USP, 5, 10 & 15mg, Rx	Mallinckrodt, Inc.	ANDA 76-353	5/6/03			
Dextroamphetamine Sulfate Extended Release Capsules USP, 5, 10 & 15mg, Rx	Barr laboratories, Inc.	ANDA 76-137	1/18/02			
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 5 mg, Rx	Eon Labs, Inc.	ANDA 40-470	9/27/02			
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, Rx	Watson Laboratories	ANDA 40-456	5/6/03			
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 5 mg, 10 mg, 20 mg, and 30 mg, Rx	CorePharma LLC	ANDA 40-444	6/19/02	<u>4/9/03</u>		

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets, 10 mg, 20 mg, and 30 mg, Rx	Eon Labs, Inc.	ANDA 40-439	6/14/02	<u>4/9/03</u>		
Dextroamphetamine Sulfate Tablets USP, 5 mg & 10 mg, Rx	Mallinckrodt Inc.	ANDA 40-436	1/29/02			
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate & Amphetamine Sulfate Tablets, 5, 10, 20 & 30 mg, Rx	Barr Laboratories, Inc.	ANDA 40-422	2/11/02			
Dextroamphetamine Sulfate Tablets USP, 10 mg, Rx	KV Pharmaceutical	ANDA 40-367	10/31/02			
Dextroamphetamine Sulfate Tablets USP, 5 mg, Rx	KV Pharmaceutical	ANDA 40-365	10/31/02			
Dextroamphetamine Sulfate Tablets USP, 5 mg and 10 mg.	Barr Laboratories, Inc.	ANDA 40-361	1/31/01	<u>06/11/02</u>	<u>06/11/02</u>	<u>06/11/02</u>
Dextroamphetamine Sulfate Tablets USP, 5 mg.	Endo Pharmaceutical Inc.	ANDA 40-299	5/13/99	<u>5/18/99</u>		<u>7/11/01</u>
Dextrose 50% Injection in Pet Abboject Vials	Abbott Laboratories	NDA 19-445/S-004 AND S-006	11/24/98	<u>11/30/98</u>		<u>3/5/99</u>
	<p>Dextrose Indications: S-004: This supplement provides for a new sub-population - Neonates and older infants for approved use as a minimal source of carbohydrates and calories in this population.</p> <p>S-006: This supplement provides for a new indication in the treatment of acute symptomatic episodes of hypoglycemia in the neonate and older infant to restore depressed blood glucose levels and control symptoms.</p>					
Dextrose Injection USP, 10%, 20%, 30%, 40%, 50%, and 70%, Rx	Baxter Healthcare	NDA 17-521/S-062 & S-063	11/14/02	<u>7/31/03</u>		
Dextrose Injection USP, 10%, 20%, 30%, 40%, 50%, and 70%, Rx	Baxter Healthcare	NDA 17-521/S-061	12/5/00			
	<p>Dextrose Indications: Indicated as a caloric component in a parenteral nutrition program. Dextrose is safe and effective for the stated indication in pediatric patients up to 18 years.</p>					
Dextrose and Potassium Chloride Injection, USP, 5%, Rx	Baxter Healthcare Corporation	NDA 17-634/S-059	1/3/03	<u>1/23/03</u>		

DHE 45 (dihydroergotamine) Injection & Migranal (dihydroergotamine) Nasal Spray,	Xcel Pharmaceuticals	NDA 20-148/S-007/S-008 005929/S32 & 33	7/31/02	<u>8/6/02</u>	<u>7/31/02</u>	
Diabinese (chlorpropamide) Tablets, USP,	Pfizer Inc.	NDA 11-641/S-058 & 11-641/S-060	5/16/02	<u>5/21/02</u>		
Diastat (diazepam rectal gel), Rx	Elan Pharmaceuticals, Inc.	NDA 20-648/S-002	4/11/01	<u>4/8/03</u>		
Dibenzylamine (phenoxybenzamine HCl) Capsules, 10 mg, Rx	Wellspring Pharmaceutical Corporation	NDA 8-708/S-022	1/15/03	<u>1/23/03</u>		
Diclofenac Potassium Tablets, 50 mg, Rx	Eon Labs manufacturing, Inc.	ANDA 75-582	2/23/01	<u>3/6/01</u>		
Diclofenac Potassium Tablets, 50 mg, Rx	Mutual Pharmaceutical Co., Inc.	ANDA 75-470	2/21/02			
Diclofenac Potassium Tablets, 50 mg, Rx	Mylan Pharmaceuticals Inc.	ANDA 75-463	7/26/99	<u>7/29/99</u>		
Diclofenac Potassium Tablets, 50 mg, Rx	Invamed Inc.	ANDA 75-229	11/25/98	<u>11/200/98</u>		
Diclofenac Potassium Tablets, 50 mg, Rx	Teva Pharmaceuticals USA	ANDA 75-219	8/6/98	<u>8/7/98</u>		
Diclofenac Potassium Tablets, 50 mg, Rx	Watson Laboratories, Inc.	ANDA 75-152	11/27/98	<u>12/1/98</u>		
Diclofenac Sodium Delayed-release Tablets USP, 50 & 75 mg, Rx	Alphapharm Pty. Ltd.	ANDA 75-281	2/12/02			
Diclofenac Sodium Delayed-release Tablets USP, 25 mg, 50 mg, 75 mg, Rx	Carlsbad Technology	ANDA 75-185	11/13/98	<u>11/16/98</u>		
Diclofenac Sodium Delayed-release Tablets USP, 25 mg, 50 mg, 75 mg, Rx	Martec Scientific	ANDA 74-986	2/26/99	<u>3/4/99</u>		<u>8/23/01</u>
Diclofenac Sodium Delayed-release Tablets USP, 50 mg & 75 mg	Sidmak Laboratories	ANDA 74-432	7/29/99	<u>8/4/99</u>		
Diclofenac Sodium Delayed-release Tablets USP, 50 mg, Rx	Novopharm Ltd.	ANDA 74-723	3/30/99	<u>4/1/99</u>		

Diclofenac Sodium extended-release Tablets USP, 100 mg, Rx	Mylan Pharmaceuticals Inc.	ANDA 76-152	12/13/01			
Diclofenac Sodium extended-release Tablets USP, 100 mg, Rx	Purepac Pharmaceutical Co.	ANDA 75-910	1/7/00			
Diclofenac Sodium extended-release Tablets USP, 100 mg, Rx	Keller & Heckman	ANDA 75-492	2/11/00	<u>2/17/00</u>		<u>6/7/01</u>
Diclofenac Sodium Ophthalmic Solution, 0.1%, Rx	Alcon Laboratories	NDA 20-809	5/4/98	<u>1/6/99</u>	<u>1/8/99</u>	<u>3/14/00</u>
Diclofenac Indication: treatment of postoperative inflammation in patients who have undergone cataract extraction.						
Dicyclomine Hydrochloride Capsules USP, 10 mg	Mylan Pharmaceuticals, Inc.	ANDA 40-319	9/14/99	<u>9/14/99</u>		
Dicyclomine Hydrochloride Capsules USP, 20 mg	Mylan Pharmaceuticals, Inc.	ANDA 40-317	9/17/99	<u>9/14/99</u>		
Dicyclomine Hydrochloride Injection USP, 20 mg, Rx	Bedford Laboratories	ANDA 40-465	6/30/03			
Dicyclomine Hydrochloride Tablets USP, 20 mg	Lannett Company Inc.	ANDA 40-230	2/26/99	<u>3/2/99</u>		<u>8/1/03</u>
Didronel (Etidronate Disodium) Tablets,	Procter and Gamble Pharmaceuticals, Inc.	NDA 17-831/S-052	3/15/02	<u>3/29/02</u>		
DIFFERIN (adapalene) Cream, 0.1%, Rx	Galderma, L.P.	NDA 20-748	5/26/00	<u>6/6/00</u>	<u>6/6/00</u>	<u>5/8/03</u>
Diflorasone Diacetate Cream USP, 0.05%	Altana Inc.	ANDA 76-263	12/20/02			
Diflorasone Diacetate Cream USP, 0.05%	Altana Inc.	ANDA 75-187	3/30/98			<u>3/5/99</u>
Diflorasone Diacetate Ointment USP, 0.05%	Altana Inc.	ANDA 75-374	4/27/99	<u>5/3/99</u>		<u>12/18/01</u>
Diflorasone Diacetate Cream USP, 0.05%, Rx	Taro Pharmaceuticals	ANDA 75-508	4/24/00	<u>4/28/00</u>		
Diflucan (Fluconazole) Tablets, Injection & Oral Powder, 150 mg, Rx	Pfizer, Inc.	NDA 19-949/S33, 19-950/S33 & 20-090/S15	8/7/02	<u>8/12/02</u>	<u>8/9/02</u>	
Digoxin Injection USP, 0.25 mg/mL, 2mL ampul, Rx	Abbott Laboratories	ANDA 40-206	8/28/98	<u>9/2/98</u>		
Digoxin Tablets USP, 0.125 mg and 0.25 mg., Rx	Caraco Pharmaceutical	ANDA 76-393	1/31/03			

	Laboratories					
Digoxin Tablets USP, 0.125 mg and 0.25 mg., Rx	Jerome Stevens Pharmaceuticals, Inc.	ANDA 76-268	7/26/02			
Digoxin Tablets USP, 0.125 mg and 0.25 mg.	Amide Pharmaceutical, Inc.	ANDA 40-282	12/23/99	<u>12/27/99</u>		<u>7/11/01</u>
Dihydroergotamine Mesylate Injection, 1 mg/mL, Rx	Paddock Laboratories, Inc.	ANDA 40-475	4/28/03			
Dihydroergotamine Mesylate Injection, 1 mg/mL, Rx	Bedford Laboratories	ANDA 40-453	6/9/03			
Dilantin-125 (phenytoin) Oral Suspension, Rx	Pfizer Pharmaceuticals	NDA 8-762/S-031	3/24/03	<u>3/26/03</u>		
Dilantin-125 (phenytoin) Oral Suspension & Dilantin (Phenytoin Sodium) Injection, USP,	Pfizer Pharmaceuticals	NDA 8-762/S-020, 021, 022 & 026 & 10-151/S-022, 029, 030, 032, 033 & 034	11/20/01	<u>2/22/02</u>		
Dilaudid (hydromorphone HCl, USP) Oral Liquid & Tablets, 1 mg/mL & 8 mg respectively, Rx	Abbott Laboratories	NDA 19-891/S-002 & 19-892/S-002	3/10/03	<u>4/1/03</u>		
Diltiazem Hydrochloride Extended-release Capsules, Rx	Biovail Laboratories Incorporated	NDA 20-939	1/28/00	<u>2/3/00</u>	<u>2/3/00</u>	<u>2/19/02</u>
Diltiazem Indication: NDA 20-939: Hypertension Dosage						
Diltiazem Hydrochloride Extended-release Capsules USP, 120 mg, 180 mg, 240 mg, & 300 mg., Rx	Keller and Heckman	ANDA 75-116	12/23/99	<u>1/4/99</u>		
Diltiazem Hydrochloride Extended-release Capsules USP, 120 mg, 180 mg, & 240 mg, Rx	Mylan Pharmaceuticals Inc.	ANDA 75-124	3/18/98			<u>3/22/99</u>
Diltiazem Hydrochloride Extended-release Capsules USP, 240 mg, Rx	Torpharm	ANDA 74-943	8/6/98	<u>8/7/98</u>		<u>8/6/03</u>
Diltiazem Hydrochloride Extended-release Capsules USP (Once-a-Day Dosage), 120 mg, 180 mg, 240 mg and 300 mg, Rx	Purepac Pharmaceutical	ANDA 74-984	12/20/99	<u>12/27/99</u>		
Diltiazem Hydrochloride Extended-release Capsules USP, 60 mg, 90 mg, & 120 mg	Biovail Corp. Intl.	ANDA 74-845	9/15/99	<u>9/24/99</u>		<u>8/22/01</u>

Diltiazem Hydrochloride Extended-release Capsules USP , 120 mg, 180 mg, 240 mg, and 300 mg.	Andrx Pharmaceuticals	ANDA 74-752	7/9/98	<u>8/16/00</u> <u>8/16/00</u>	<u>8/16/00</u>	
Diltiazem Hydrochloride Injection , 100 mg/mL, Rx	Abbott Laboratories	ANDA 75-853	12/17/02			
Diltiazem Hydrochloride Injection , 5 mg/mL, Rx	International Medication Systems, Ltd	ANDA 75-749	11/21/01	<u>4/15/03</u>		
Diltiazem Hydrochloride Injection , 5 mg/mL, Rx	Apotex Corp.	ANDA 75-375	9/30/99	<u>10/1/99</u>		
Diltiazem Hydrochloride Injection , 5 mg/mL	Abbott Laboratories	NDA 74-941	8/15/99			<u>4/23/03</u>
Diltiazem Hydrochloride Injection , 5 mg/mL,	Taylor Pharmaceuticals	ANDA 75-086	4/9/98			<u>8/24/01</u>
Diltiazem Hydrochloride Injection , 5 mg/mL, [packed in 5 mL (25 mg), & 10 mL (50 mg) vials].	Meridian Medical Technologies, Inc.	ANDA 75-106	4/29/99	<u>5/4/99</u>		
Diltiazem Hydrochloride Injection , 5 mg/mL, 5 mL Syringes, Rx	Abbott Laboratories	ANDA 75-004	2/16/00	<u>2/24/00</u>		
Diltiazem Hydrochloride Injection , 5 mg/mL, (25 mL Vial), Rx	Gensia Sicor Pharmaceuticals, Inc.	ANDA 74-894/S1	4/19/02			
Dimethyl Sulfoxide Irrigation Solution USP , 50% 50%, Rx	Bioniche Pharma Ltd.	ANDA 76-185	11/29/02			
Diovan Tablets , Rx	Novartis Pharmaceuticals	NDA 020818	3/06/98			<u>8/13/03</u>
Diovan (valsartan) Capsules , Rx	Novartis Pharmaceuticals Corporation	NDA 20-665/S-004	11/27/98			
Diovan (valsartan) Capsules & Tablets , Rx	Novartis Pharmaceuticals Corporation	NDA 21-283	7/18/01		<u>5/5/03</u>	<u>8/12/03</u>
Diovan (valsartan) Capsules & Tablets , Rx	Novartis Pharmaceuticals Corporation	NDA 20-665/S-016 & 21-283/S-001	8/14/02	<u>8/21/02</u>	<u>8/14/02</u>	<u>2/3/03</u>
Diovan (valsartan) Tablets , Rx	Novartis Pharmaceuticals Corporation	NDA 21-283/S-002	4/5/02	<u>4/16/02</u>	<u>7/25/02</u>	<u>7/25/02</u>
Diovan HCT	Novartis	NDA 20-	1/15/03	<u>1/23/03</u>		<u>7/8/03</u>

(valsartan/hydrochlorothiazide) Tablets, 80/12.5 mg and 160/25 mg Rx	Pharmaceuticals Corp.	818/S16				
Diovan HCT (valsartan/hydrochlorothiazide) Tablets, 80/12.5 mg and 160/12.5 mg.	Novartis Pharmaceuticals Corp.	NDA 20-818/S12	1/17/02	<u>2/5/02</u>		
Dipentum (olsalazine sodium) Capsules,	Pharmacia & Upjohn Company	NDA 19-715/S-021	8/9/02	<u>8/12/02</u>		
Dipentum (olsalazine sodium) Capsules.	Pharmacia & Upjohn Company	NDA 19-715/S-018	1/18/02	<u>2/5/02</u>		
Diphenhydramine Hydrochloride Injection USP, (Preservative-Free), 50 mg/ml	American Pharmaceutical Partners, Inc.	ANDA 40-466	5/28/02	<u>4/9/03</u>		
Diphenhydramine Hydrochloride Injection USP, (Preservative-Free), 50 mg/ml	Abbott Laboratories	ANDA 40-140	11/20/98	<u>11/20/98</u>		
Diphenoxylate Hydrochloride & Atropine Sulfate Tablets, 2.5 mg/0.025, Rx	Able Laboratories, Inc.	ANDA 40-395	11/27/00	<u>11/27/00</u>		
Diphenoxylate Hydrochloride & Atropine Sulfate Tablets, 2.5 mg/0.025, Rx	Par Pharmaceuticals	ANDA 40-357	5/2/00			
Diprivan (propofol) Injectable Emulsion, 10 mg/mL, Rx	AstraZeneca LP	NDA 19-627/S-35	2/23/01	<u>3/14/01</u>	<u>3/14/01</u>	
Diprolene AF (Betamethasone Dipropionate) Cream, 0.05%, Rx	Schering Corporation	NDA 19-555/S8 & S16	10/3/01	<u>11/6/01</u>	<u>11/6/01</u>	<u>11/14/01</u>
Diprosone AF (Betamethasone Dipropionate) Cream, 0.05%, Rx	Schering Corporation	NDA 17-536/S16 & S8	10/3/01			
Diprosone (Betamethasone Dipropionate) Cream, 0.05%, Rx	Schering Corporation	NDA 17-536/S24 & S18	10/3/01	<u>11/5/01</u>	<u>11/5/01</u>	<u>11/14/01</u>
Diprosone (Betamethasone Dipropionate) Lotion, 0.05%, Rx	Schering Corporation	NDA 17-781/S22 & S15	10/3/01	<u>11/6/01</u>	<u>11/6/01</u>	<u>11/14/01</u>
Diprosone (Betamethasone Dipropionate) Ointment, 0.05%, Rx	Schering Corporation	NDA 17-691/S19 & S24	10/3/01	<u>11/5/01</u>	<u>11/5/01</u>	<u>11/14/01</u>
Dipyridamole Injection, 5 mg/mL, Rx	Apotex Corp.	ANDA 75-769	11/27/02			
Dipyridamole Single-Dose Vials, 5	American	ANDA 74-956	9/30/98	<u>9/30/98</u>		<u>9/25/02</u>

mg/mL, 2 mL and 10 mL, Rx	Pharmaceutical Partners					
DisperMox (Amoxicillin) Tablets for Oral Suspension, Rx	Ranbaxy	ANDA 65-080	8/11/03			
Ditropan XL Tablets, Syrup & Extended Release Tablets, 5 mg, 10 mg	Johnson & Johnson Pharmaceutical	NDA 17-577/S33, S32, 18-211/S16, S14 & 20-897/S9, S10	4/15/03		<u>4/16/03</u>	
Ditropan XL Tablets, 5 mg, 10 mg	Alza Corporation	NDA 20-897	12/16	<u>12/18</u>	<u>12/17</u>	<u>7/8/99</u>
Ditropan XL Indication: Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency						
Divalproex Sodium Delayed-release Tablets, 125 mg, 250 mg, and 500 mg, Rx Tentatively Approved	Torpharm Inc.	ANDA 75-112	5/31/01	<u>6/5/01</u>		
Diovan (Valsartan) Tablet, Rx	Novartis Pharmaceuticals Corporation	NDA 21-283	7/18/01			
Diovan Indications: Indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.						
Dobutamine in 5% Dextrose Injection	Abbott Laboratories	NDA 20-201/S-013	4/11/01	<u>4/8/03</u>		
Dobutamine Hydrochloride & 5% Dextrose Injection USP, Rx	Baxter Healthcare Corp.	NDA 20-255/S009 & S011	7/24/03	<u>7/28/03</u>		
Dobutamine Hydrochloride & 5% Dextrose Injection USP, Rx	Baxter Healthcare Corp.	NDA 20-255/s006	6/14/00			<u>6/4/01</u>
Dobutamine Injection USP, 12.5 mg (base)/mL, Rx	Luitpold Pharmaceuticals	ANDA 74-545	6/25/98	<u>6/26/98</u>		
Dobutamine Injection USP, 12.5 mg/mL; 100 mL	Marsam Pharmaceuticals, Inc.	ANDA 74-995	3/31/98			<u>3/19/99</u>
Dobutrex Solution (Dobutamine) Injection,	Eli Lilly and Company	NDA 17-820/S-037	7/23/02	<u>7/24/02</u>		<u>9/24/02</u>
Dopamine Hydrochloride and 5% Dextrose Injection, USP,	Baxter Healthcare Corporation	NDA 19-615/S-017	6/20/02	<u>6/24/02</u>		
Dopamine Hydrochloride and 5% Dextrose Injection, USP, in Plastic Container, PL 2207.	Baxter Healthcare Corporation	NDA 19-615/S-012	4/17/01	<u>5/3/01</u>		<u>8/17/01</u>
Dopamine Hydrochloride in 5% Dextrose Injection in Flexible	Abbott Laboratories	NDA 18-826/S-027	4/10/01	<u>4/3/03</u>		<u>7/28/03</u>

Container, Rx						
Dopram (doxapram hydrochloride injection, USP) Injectable	Wyeth-Ayerst Research	NDA 14-879/S-036	8/23/01	<u>11/21/02</u>		
Doral (quazepam) Tablets,	Wallace Laboratories	NDA 18-708/S-014	11/14/02	<u>7/29/03</u>		
Doryx (coated doxycycline hyclate pellets) Capsules, Rx	F. H. Faulding & Co, Ltd.	NDA 50-582/S-021	6/5/03			
Doryx (coated doxycycline hyclate pellets) Capsules,	F. H. Faulding & Co, Ltd.	NDA 50-582/S-016	6/18/02	<u>6/24/02</u>		
Doubtrex (Dobutamine HCl) Injection, 12.5 mg/mL, Rx	Lilly Research Laboratories	NDA 17820/S-036	7/29/98			<u>8/8/01</u>
Dovonex Ointment, 0.005%, Rx	Westwood Squibb Pharmaceutical Inc.	NDA 20-273/SE8-004	7/7/99	<u>7/28/99</u>		<u>7/6/00</u>
Doxapram Hydrochloride Injection, 20 mg/mL, Rx	Bedford Laboratories	ANDA 76-266	1/10/03			
Doxazosin Mesylate Tablets, 1 mg (base), 2 mg (base), 4 mg (base) and 8 mg (base), Rx <i>Tentatively Approved</i>	Geneva Pharmaceuticals	ANDA 75-301	2/26/99	<u>3/4/99</u>		
Doxazosin Mesylate Tablets, 1 mg (base), 2 mg (base), 4 mg (base) and 8 mg (base), Rx	Teva Pharmaceuticals USA	ANDA 75-353	1/12/01	<u>3/6/01</u>		
Doxazosin Mesylate Tablets, 1 mg (base), 2 mg (base), 4 mg (base) and 8 mg (base), Rx <i>Tentatively Approved</i>	ESI Lederle, Inc.	ANDA 75-490	8/30/99	<u>9/2/99</u>		
Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg tablets, Rx	Chelsea Laboratories, Inc.	ANDA 75-426	10/18/00	<u>10/30/00</u>		
Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg tablets, Rx	Invamed Inc.	ANDA 75-432	10/18/00	<u>10/30/00</u>		
Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg tablets, Rx	Zenith Goldline Pharmaceuticals Inc.	ANDA 75-453	10/18/00	<u>10/30/00</u>		
Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg tablets, Rx, Tentatively approved on July 26, 2000	Zenith Goldline Pharmaceuticals Inc.	ANDA 75-453	7/26/00	<u>10/30/00</u>		

Doxazosin Mesylate Tablets, 1 mg (base), 2 mg (base), 4 mg (base) and 8 mg (base), Rx	Genpharm, Inc.	ANDA 75-466	10/18/00	<u>11/6/00</u>		
Doxazosin Mesylate Tablets, 1 mg (base), 2 mg (base), 4 mg (base) and 8 mg (base), Rx	Mylan Pharmaceuticals, Inc.	ANDA 75-509	10/19/00	<u>11/6/00</u>		
Doxazosin Mesylate Tablets, 1 mg (base), 2 mg (base), 4 mg (base) and 8 mg (base), Rx	TEVA Pharmaceuticals	ANDA 75-536	10/18/00	<u>11/6/00</u>		
Doxazosin Mesylate Tablets, 1 mg (base), 2 mg (base), 4 mg (base) and 8 mg (base), Rx <i>Tentatively Approved</i>	Novopharm Limited	ANDA 75-536	7/24/00	<u>11/6/00</u>		
Doxazosin Mesylate Tablets, 1 mg (base), 2 mg (base), 4 mg (base) and 8 mg (base), Rx	Purepac Pharmaceutical Co.	ANDA 75-574	10/18/00	<u>11/7/00</u>		
Doxazosin Mesylate Tablets, 1 mg (base), 2 mg (base), 4 mg (base) and 8 mg (base), Rx <i>Tentatively Approved</i>	Purepac Pharmaceutical Co.	ANDA 75-574	10/28/99	<u>12/29/99</u>		
Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg tablets, Rx	TorPharm	ANDA 75-580	10/18/00	<u>11/7/00</u>		
Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg tablets, Rx, Tentatively approved on July 26, 2000	TorPharm	ANDA 75-580	7/26/00	<u>11/7/00</u>		
Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg (base), Rx	KV Pharmaceutical Company	ANDA 75-609	10/18/00	<u>11/7/00</u>		<u>8/6/03</u>
Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg (base), Rx	Eon Labs Manufacturing, Inc.	ANDA 75-646	10/18/00	<u>11/7/00</u>		
Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg (base), Rx	Sidmak Laboratories, Inc.	ANDA 75-750	6/8/01	<u>6/8/01</u>		
Doxepin Hydrochloride Oral Solution USP, 10 mg (base)/mL.	Silarx Pharmaceuticals, Inc.	ANDA 74-721	12/29/98	<u>12/29/98</u>		
Doxil (doxorubicin HCl liposome) Injection, Rx	ALZA Corporation	NDA 50-718/S-016	12/17/02			
Doxil (doxorubicin HCl liposome) Injection, Rx	ALZA Corporation	NDA 50-718/S-010	1/10/02	<u>2/8/02</u>		
Doxil (doxorubicin HCl liposome)	ALZA Corporation	NDA 50-718/S-	6/28/99	<u>6/30/99</u>	<u>6/30/99</u>	

Injection, 50 mg/m2, Rx		006				
	Doxil Injection: treatment of metastatic carcinoma of the ovary in patients with disease that is refractory to both paclitaxel- and platinum-based chemotherapy regimens.					
Doxorubicin Hydrochloride Injection, 10, 20, 50, and 150 & 10, 20, 50, 75, 150, and 200 mg, Rx	Pharmacia & Upjohn Company	NDA 50-467/S-068/S-069 & 50-629/S-014/S-016	5/8/03	<u>7/9/03</u>		
Doxycycline Capsules USP, 50 mg & 100 mg	Par Pharmaceuticals Inc.	ANDA 65-055	12/1/00	<u>2/28/01</u>		
Doxycycline Capsules USP, 50 mg & 100 mg	Ranbaxy Laboratories Ltd.	ANDA 65-053	11/22/00	<u>11/27/00</u>		
Doxycycline Capsules USP, 50 mg & 100 mg	Halsey Drug Company, Inc.	ANDA 65-041	4/28/00	<u>4/28/00</u>		
Doxycycline Capsules USP, 50 mg & 100 mg, Rx	Eon Labs Manufacturing Inc.	ANDA 65-032	6/30/00	<u>10/30/00</u>		
Doxycycline Tablets, 75 mg, Rx	Par Pharmaceutical, Inc.	ANDA 65-070/S5 & S6	12/30/02			
Doxycycline Tablets, 50 mg & 100 mg, Rx	Par Pharmaceutical, Inc.	ANDA 65-070	12/15/00	<u>2/28/01</u>		
Doxycycline Hyclate Tablets, 100 mg, Rx	West-Ward Pharmaceutical	ANDA 65-095	7/2/03			
Drixoral Cold & Flu & Allergy Sinus Extended Release Tablet,	Schering-Plough	NDA 19-453/S-014	3/28/03	<u>4/14/03</u>		
Droxia (hydroxyurea) Capsules, USP)	Bristol-Myers Squibb Company	NDA 16-295/S-036	6/26/03	<u>7/6/03</u>	<u>7/8/03</u>	
Duagen (Dutasteride) Soft gel Capsules, 0.5 mg, Rx	GlaxoSmithKline	NDA 21-319	11/20/01			<u>1/14/02</u>
	Dutasteride Indications: for the signs and symptoms of benign prostatic hyperplasia.					
DUAC (clindamycin, 1% - benzoyl peroxide, 5%) Topical Gel,	Stiefel Laboratories, Inc.	NDA 50-741	8/26/02	<u>8/30/02</u>	<u>8/26/02</u>	<u>4/27/03</u>
Duocaine (lidocaine HCl-bupivacaine HCl) Injection, 1%/0.375%, Rx	Amphastar Pharmaceuticals, Inc.	NDA 21-496	5/23/03	<u>6/9/03</u>	<u>6/9/03</u>	
DuoNeb (3.0 mg albuterol sulfate and 0.5 mg ipratropium bromide per 3 mL) Inhalation Solution,Rx	Dey Laboratories	NDA 20-950	3/21/01	<u>3/5/02</u>	<u>3/5/02</u>	<u>3/5/02</u>

	DuoNeb Indications: treatment of bronchospasm associated with COPD in patients who require more than one bronchodilator.					
Duragesic (fentanyl transdermal system)	Alza Corporation	NDA 19-813/S-023 and S-030	4/11/01	<u>4/8/03</u>		
Duramorph (morphine sulfate injection) and Infumorph, (preservative-free morphine sulfate sterile solution)	Elkins-Sinn	NDA 18-565/S-010	6/26/03	<u>7/6/03</u>		
Duricef® (cefadroxil monohydrate, USP) Capsules, Oral Suspension & Tablets,	Bristol-Myers Squibb Company	NDA 50-512/S-044, 50-527/S-020 & 50-528/S-018	5/3/02	<u>5/21/02</u>	<u>5/6/02</u>	
Dynabac (dirithromycin) Tablets,	Eli Lilly and Company	NDA 50-678/S-010	5/23/02	<u>6/3/02</u>		

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